REMARKS

In response to the Office Action dated November 21, 2005, Applicants respectfully request that the above amendments be entered and the following remarks be considered. Claims 1-3, 6-14, 17, 18, and 20-24 are currently pending in the application. Claims 1-3, 8, 11, 12, 17, and 22 have been amended. Claims 1-14 and 17-24 are believed to be in condition for allowance and such favorable action is respectfully requested..

Objections

Paragraph [0016] of the specification has been objected to for failing to provide proper antecedent basis for the claimed subject matter. Applicants have amended paragraph [0016] to provide proper antecedent basis. Applicants submit that no new matter has been added as the matter was contained in the claims as originally filed. As such, Applicants request withdrawal of the objection.

35 U.S.C. § 112, Second Paragraph, Rejections

Claims 2, 3, 8-13, 17, 18, and 20-24 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action states that claims 2 and 17 recite "may be" and is unclear as to the meaning. The Office Action states that claims 2, 12, and 17 recite the term "substantially" which does not provide the standard for ascertaining the requisite degree. The Office Action states that claims 2, 12, and 17 recite "may be substantially" which is/are not clear as to the object(s) and/or step(s), if any, required for performing conclusion or achieving a state of conclusion. Applicants submit that claims 2, 12

and 17 have been amended. As such, Applicants request withdrawal of the § 112 rejection of claim 17.

The Office states that claims 6 and 20 recite "total anti-neutrophil cytoplasmic antibodies" and is unclear as to how "antibodies" is modified by "total." Applicants respectfully submit that the term "total" is intended to describe the complete protein and smaller degraded forms that may occur in the gut following protease and acid digestion. Applicants submit that polyclonal antibodies bind all forms of the protein. As such, Applicants request withdrawal of the §112 rejection of claims 6 and 20.

It is stated in the Office Action that claims 8, 11, and 22 recite "the sample with neutrophil cytoplasmic antigens" which lacks antecedent basis. Applicants have amended claims 8, 11 and 22 to provide antecedent basis for this claim limitation. Further, Applicants submit that the specification has been amended to provide antecedent support, therefore, Applicants request withdrawal of the § 112 rejection of claims 8, 11, and 22. Applicants submit that no new matter has been added by way of these amendments to the specification as the matter was contained in the claims as originally filed.

It is stated in the office action that claims 9, 11, and 23 recite "the treated sample with polyvalent antibodies" lacks antecedent basis. The Office states that claims 9, 11, and 23 recite "contacting the treated sample....to create a readable sample" lacks antecedent support in the specification. Applicants submit that paragraph [0016] of the specification, as amended, provides the support for contacting the treated sample to create a readable sample. Applicants request withdrawal of the § 112 rejection of claims 9, 11, and 23.

The Office states that claims 8, 9, 11, 22, and 23 recite "to create" and is unclear whether the act or process of creating is completed or performed, or merely intended. Applicants submit that "the fecal sample" is coming in contact with "neutrophil cytoplasmic antigens," thus

creating a "treated sample." In claims 9, 11 and 23, "the treated sample" is contacted with "polyvalent antibodies," thus creating a "readable sample." Therefore, each act, when performed, creates a "treated sample" or a "readable sample." As such, Applicants request withdrawal of the § 112 rejection of claims 8, 9, 11, 22, and 23.

102(e) Rejections

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP § 2131.

Claims 1-3, 6, 7, 14, 17, 18, 20, and 21 have been rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6, 667,160 to Fine ("Fine"). Claim 1 of the present invention has been amended to be drawn to a method for determining whether there is an elevated level of anti-neutrophil cytoplasmic antibodies are present in a fecal sample, wherein an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis. As Fine does not teach or suggest determining whether an elevated level of anti-neutrophil cytoplasmic antibodies are present in a fecal sample, where an elevated of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis, Applicants request withdrawal of the rejection of amended claim 1.

Rather, Fine teaches a method for diagnosing food sensitivities with the detection of antitissue transglutaminase antibodies. The antitissue transglutaminase antibody detection taught by Fine is not the determination of anti-neutrophil cytoplasmic antibodies recited in claim 1. Antitissue transglutaminase antibodies are different from anti-neutrophil cytoplasmic

antibodies. In column 12, lines 23-28, diagnosing gluten sensitivity or celiac sprue by the detection of antitissue transglutaminase is described, but there is not mention of determining whether an elevated level of anti-neutrophil cytoplasmic antibodies are present in a fecal sample, where an elevated of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis. As Fine does not teach or suggest the detection of anti-neutrophil cytoplasmic antibodies as an indicator for ulcerative colitis, Applicants respectfully request that the rejection of amended claim 1 be withdrawn.

Independent claim 17 is drawn to a method for determining whether anti-neutrophil cytoplasmic antibodies are present in the sample; and if so, a diagnosis of ulcerative colitis is concluded. As Fine does not teach or suggest determining whether a fecal sample contains anti-neutrophil cytoplasmic antibodies to aid diagnosis of ulcerative colitis, Applicants request withdrawal of the rejection of amended claim 1.

Rather, Fine teaches a method for diagnosing food sensitivities with the detection of antitissue transglutaminase antibodies; however, the antitissue transglutaminase antibody taught by Fine is not the anti-neutrophil cytoplasmic antibodies recited in claim 1. Fine does not teach or suggest that determining whether a fecal sample has an elevated level of anti-neutrophil cytoplasmic antibodies to aid diagnosis of ulcerative colitis. In column 12, lines 23-28, diagnosing gluten sensitivity or celiac sprue by the detection of antitissue transglutaminase is described, but there is not mention of the detection of anti-neutrophil cytoplasmic antibodies as an indicator for ulcerative colitis. As Fine does not teach or suggest that determining whether a fecal sample has an elevated level of anti-neutrophil cytoplasmic antibodies to diagnose ulcerative colitis, Applicants respectfully request that the rejection of amended claim 1 be withdrawn.

As dependent claims 3, 6, 7, 14, 18, 20, and 21 dependent directly from claims 1 and 17, Applicants submit that these claims are allowable for at least the above reasons.

CONCLUSION

Each of claims 1-3 6-14 and 17, 18 and 20-24 is believed to be in condition for allowance, and a timely notice of allowance solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

It is believed that no additional fee is due in conjunction with the present Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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